#### UNITED STATES DISTRICT COURT WESTERN DISTRICT OF TEXAS SAN ANTONIO DIVISION

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KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC., and WAKE FOREST UNIVERSITY **HEALTH SCIENCES** 

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Plaintiffs,

VS.

CIVIL ACTION NO. SA-03-CA-0832-RF

BLUESKY MEDICAL CORPORATION, MEDELA AG, MEDELA, INC., and PATIENT CARE SYSTEMS, INC.

Defendants.

#### PLAINTIFFS' FIRST AMENDED COMPLAINT

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Plaintiffs, Kinetic Concepts, Inc., KCI Licensing, Inc., and KCI USA, Inc. (collectively, "KCI"), and Wake Forest University Health Sciences (individually, "Wake Forest") and (collectively, "Plaintiffs") files this First Amended Original Complaint for damages and injunctive relief against BlueSky Medical Corporation ("BlueSky"), Medela AG, Medela Inc. and Patient Care Systems, Inc. ("PCS") (collectively, "Defendants"). In support of their First Amended Complaint, Plaintiffs allege as follows:

#### I. PARTIES

Plaintiff Kinetic Concepts, Inc. is a Texas corporation with its principal place of 1. business in San Antonio, Texas. Kinetic Concepts, Inc., by and through its subsidiaries, is a leader in the development, manufacture and distribution of specialty therapeutic medical devices.

- 2. Plaintiff KCI USA, Inc. ("KCI USA") is a corporation organized under the laws of the State of Delaware having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230. KCI USA is a wholly owned subsidiary of Kinetic Concepts, Inc.
- 3. Plaintiff KCI Licensing, Inc. ("KCI Licensing") is a corporation organized under the laws of the State of Delaware having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230. KCI Licensing is a wholly owned subsidiary of Kinetic Concepts, Inc.
- 4. Plaintiff Wake Forest is a non-profit corporation organized under the laws of the State of North Carolina having its principal place of business at Medical Center Boulevard, Winston-Salem, North Carolina 27157-1023. Wake Forest is a wholly-controlled subsidiary of Wake Forest University.
- 5. Defendant BlueSky is a California corporation, incorporated in April of 2002, with its principal place of business in La Costa, California. BlueSky may be served with process by serving its registered agent, Richard Weston, at 6965 El Camino Real, Suite 105-602, La Costa, California 92009.
- 6. Defendant Medela AG is a Swiss company having its principal place of business at Lattchstrasse 4, 6341 Baar/Switzerland. Medela AG may be served pursuant to the Hague Convention by forwarding a copy of this Complaint and Summons to the receiving authority location in Switzerland.
- 7. Defendant Medela Inc. is a Delaware corporation with its principal place of business at 1101 Corporate Dr., McHenry, Illinois 60050. Medela Inc. may be served with process by serving its registered agent, Joseph P. Della Maria, Jr. at 55 W. Monroe Street, Suite

3900, Chicago, Illinois 60603. Defendant Medela Inc. is a wholly owned subsidiary of Medela AG, such that Medela AG and Medela Inc. (collectively "Medela") are affiliates of one another.

8. Defendant PCS is a Texas corporation having its principal place of business at 5802 Gardendale Dr., Houston, Texas 77092. PCS is a distributor of BlueSky's products and has an office in San Antonio, Texas. PCS may be served with process by serving its registered agent Barry W. Bearden at 789 Bradfield, Houston, Texas 77027.

#### II. JURISDICTION AND VENUE

- 9. This case arises under the federal patent, trademark and unfair competition laws, 35 U.S.C. § 1 *et seq.* and 15 U.S.C. § 1050 *et seq.*, and therefore this Court has jurisdiction under 28 U.S.C. §§ 1331, 1338(a)(b). This Court has subject matter jurisdiction over the state law claims pursuant to the doctrine of supplemental jurisdiction.
- 10. This Court has personal jurisdiction over the Defendants. Defendants regularly conduct business in this District and have committed acts of infringement and other torts alleged herein within the state of Texas and within this judicial district.
- 11. Venue is proper in this district under 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b) and 1400(b) because the acts and transactions constituting the violations alleged herein, occurred in part in this judicial district and the Defendants are found and transact business in this judicial district. Venue is also proper in this district under 28 U.S.C. § 1391(c) because the Defendants are corporations that are subject to personal jurisdiction in this district.

#### III. BACKGROUND

12. Kinetic Concepts, Inc., by and through its subsidiaries KCI USA and KCI Licensing (collectively, "KCI"), is a leader in the development, manufacture and distribution of

specialty therapeutic medical devices. KCI is a Medicare participating supplier, providing medical equipment to Medicare beneficiaries throughout the Untied States.

- 13. Several of KCI's product lines feature products that provide wound care benefits for patients. KCI's wound care product lines include variations of the Vacuum Assisted Closure<sup>®</sup> System ("V.A.C.<sup>®</sup> System"). The designations "V.A.C." and "Vacuum Assisted Closure" are federally registered trademarks of KCI Licensing, Inc. A true and correct copy of U.S. Trademark Reg. No. 1,982,349 for the mark "V.A.C." is attached hereto as **Exhibit "A"**. A true and correct copy of U.S. Trademark Reg. No. 2,657,666 for the mark "VACUUM ASSISTED CLOSURE" is attached hereto as **Exhibit "B"**. The V.A.C. System is marketed and sold by KCI under both the registered V.A.C.<sup>®</sup> mark and the registered Vacuum Assisted Closure<sup>®</sup> mark.
- 14. The V.A.C. System is comprised of a negative pressure wound therapy pump unit, a porous dressing for application over an open wound, an occlusive adhesive drape placed over the dressing and sealed to the skin around the wound, and a disposable canister. The V.A.C. System has been very effective and represents a significant technological advance in wound healing.
- 15. The commercialization of the V.A.C. System marked a drastic departure from the simple application of suction that has long been used to facilitate the removal of excessive fluid that naturally pools in wounds. The unique V.A.C. System dramatically revolutionized wound care by providing effective treatment for difficult-to-treat and chronic wounds.
- 16. The V.A.C. System incorporates certain novel features and characteristics invented by researchers working on behalf of Wake Forest University in Winston-Salem, North Carolina. In recognition of the technological advances made by these researchers, the U.S.

Patent and Trademark Office issued to Wake Forest University U.S. Patent No. 5,636,643 ("'643 patent"), which was subsequently assigned to Wake Forest. A true and correct copy of the '643 patent is attached hereto as **Exhibit "C"**.

- 17. The '643 patent, entitled "Wound Treatment Employing Reduced Pressure," was duly and lawfully issued on June 10, 1997, and is extant and enforceable until its expiration date of June 10, 2014. Wake Forest is the true and record owner of the '643 patent.
- 18. Kinetic Concepts, Inc. is the exclusive licensee of the '643 patent, by virtue of a written license agreement effective October 6, 1993 with Wake Forest. Pursuant to that license agreement, KCI has the exclusive worldwide right to make, have made, use, lease and sell products incorporating the inventions covered by the '643 patent.
- 19. In recognition of additional technological advances, the U.S. Patent and Trademark Office has also issued U.S. Patent No. 4,969,880 (the "880 patent"). The '880 patent, entitled "Wound Dressing and Treatment Method," was duly and lawfully issued on November 13, 1990. A true and correct copy of the '880 patent is attached hereto as **Exhibit** "**D**".
- 20. All right, title and interest in and to the '880 patent was assigned to Kinetic Concepts, Inc. by written assignment dated August 16, 1994 and recorded in the Patent and Trademark Office on June 10, 1996 at Reel 8119 and Frame 0119. KCI subsequently assigned all right, title and interest in and to the '880 patent to KCI Licensing by written assignment dated September 19, 2001 and recorded in the Patent and Trademark Office on September 25, 2001 at Reel 0122190 and Frame 0150. The '880 patent is extant and enforceable. At all times relevant to the acts complained of herein, KCI Licensing has been the true and record owner of the '880 patent.

- 21. Medela is a manufacturer of suction pumps used in the medical field. On multiple occasions, Medela AG and its subsidiaries and distributors have improperly attempted to commercialize their suction pumps for use with specialized dressings to promote wound healing, and KCI has taken steps to resolve such improper commercialization attempts.
- 22. On March 23, 2001, in the course of appealing an injunction that prohibited Medela's German subsidiary from distributing Medela's VARIO pump for applications like those of the V.A.C. System, Medela's German subsidiary agreed to a written settlement (the "German Settlement"), which in part stated that it would cease and desist from selling, leasing, and/or advertising its VARIO model suction pump (the "Vario") and/or causing the Vario to be offered, distributed, sold and/or advertised for the purpose of the vacuum assisted closure of wounds. A true and correct copy of the English translation of the written minutes of the German Settlement, dated March 23, 2001, is attached hereto as **Exhibit "E"**.
- 23. On October 3, 2001, the District Court of Zurich (Switzerland) entered a settlement agreement between KCI and Medela AG (the "Swiss Settlement") that prohibits Medela AG from selling, leasing, and/or advertising the Vario and/or causing the Vario to be offered, distributed, sold, and/or advertised for the purpose of vacuum assisted closure of wounds. A true can correct copy of the Zurich court's order is attached hereto as **Exhibit "F"**.
- 24. On December 16, 2002, Medela AG agreed that the Vario is not suitable and is not to be used for the purpose of a wound healing system like the V.A.C. System. Medela AG further agreed to cease and desist from selling or offering to sell the Vario as suitable for such purposes, rather than for the purpose of suctioning secretions out of wounds. A true and correct copy of Medela's written "STATEMENT", dated December 16, 2002 that memorializes and embodies such agreements is attached hereto as **Exhibit "G"**. Medela further agreed to draw

attention to third parties for their inappropriate use or commercialization of the Vario pump as a wound healing system for vacuum assisted closure of wounds by such third parties. In particular, Medela agreed through an attached Schedule A to the STATEMENT (the "Schedule A") to give written notice to certain named distributors that the Vario is not suitable and is not to be used for the purpose of a wound healing system for vacuum assisted closure of wounds. A true and correct copy of the Schedule A is attached hereto as Exhibit "H". In furtherance of the agreements reached between KCI and Medela, Medela' Dutch subsidiary signed a similar statement to that of the STATEMENT, on February 4, 2003 (the "Dutch Statement"). A true and correct copy the Dutch Statement is attached hereto as Exhibit "I"

25. BlueSky was incorporated by Richard Weston, a former Medela employee, in April of 2002 and appears to have been created for the purpose of trading on the goodwill of KCI and causing injury to KCI. BlueSky markets, distributes and packages a "Versatile 1" pump that is manufactured by Medela. The Versatile 1 pump is substantially similar to the Vario pump that was the subject of Medela's April 2001 German Settlement, October 2001 Swiss Settlement (collectively "the Settlements"), December 2002 Statement, and February 2003 Dutch Statement (collectively "the Statements") referenced above. BlueSky also markets, packages and distributes disposable dressing kits (the "Blue Sky Dressings") that are commercialized for use with the Versatile 1 pump (collectively the "Versatile 1 System"). The BlueSky Dressings are labeled as either "Chariker-Jeter" wound drainage kit or "Wooding-Scott" wound drainage kit. BlueSky's "Chariker-Jeter" dressing kit contains specific instructions on how to use the dressing with the Versatile 1 pump.

- 26. Following requests from KCI, Medela AG has affirmed its obligations under the Statements, but has failed and/or refused to take any remedial action in relation to BlueSky's distribution and marketing of the Versatile 1 System.
- 27. BlueSky has engaged in a disparaging public marketing campaign through which BlueSky and its distributors have made claims of wound healing in connection with its Versatile 1 System.
- 28. BlueSky, PCS and BlueSky's other distributors are participating in false advertising of the Versatile 1 System.
- 29. BlueSky, PCS, and others under BlueSky's control are promoting, describing, and representing the Versatile 1 System in ways that, directly and by implication, are false and misleading.
- 30. BlueSky is maliciously attempting to damage KCI by disparaging KCI and its products.
- 31. Defendants have promoted and are promoting the Versatile 1 System under the designations "Negative Pressure Wound Therapy" and "Vacuum Assisted Wound Therapy," "V.A.C." and other confusingly similar designations.
- 32. BlueSky has made public statements and representations that falsely and maliciously characterize KCI products.

#### IV. CAUSES OF ACTION

#### **COUNT ONE: BREACH OF CONTRACT**

- 33. Paragraphs 1 through 32 are repeated and realleged as if fully set forth herein.
- 34. The Settlements between KCI and Medela and the Statements by Medela constitute valid, subsisting and enforceable contracts. KCI has not breached the contracts and

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has fulfilled all obligations under the contracts. Any and all conditions precedent to the contracts have been satisfied.

- 35. Medela has breached the Settlements and Statements in various ways, including the re-labeling and sale of the Vario model suction pump as the Versatile 1 pump for use in negative pressure wound therapy, with dressing kits including Wooding-Scott and Chariker-Jeter wound drainage kits.
- 36. Medela's breaches of the Settlements and Statements have been material and have not been cured, and have caused KCI actual damages, all without legal justification or excuse.
- 37. Medela's breaches of the Settlements and Statements entitle KCI to recover its actual damages resulting from those breaches.
- 38. Pursuant to Section 38.001 of the Texas Civil Practice and Remedies Code, or other applicable law, KCI is entitled to recover its attorney's fees and costs incurred in prosecuting its claim for breach of contract against Medela.

#### **COUNT TWO: FEDERAL PATENT INFRINGEMENT**

- 39. Paragraphs 1 through 38 are repeated and realleged as if fully set forth herein.
- 40. Defendants' Versatile 1 System, in whole or in part, incorporates the invention of the '643 patent exclusively licensed to KCI and/or the '880 patent owned by KCI Licensing. Manufacture, sale and use of the Versatile 1 System infringes the '643 and/or '880 patents either literally or under the doctrine of equivalents.
- 41. Defendants are knowingly directly infringing, inducing infringement or contributorily infringing the '643 and/or '880 patents within this District and elsewhere, without leave or license from KCI, all to KCI's substantial damage. Defendants will continue to do so unless enjoined from it by this Court.

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- 42. Said direct or contributory infringement of the '643 and/or '880 patents, or the active inducement of others to infringe the '643 and/or '880 patents, is willful and is damaging KCI, and KCI will suffer additional and irreparable damage unless this Court enjoins BlueSky from continuing to directly or contributorily infringe or induce others to infringe the '643 and/or '880 patents.
- 43. Unless enjoined by this Court, Defendants will continue to deliberately and willfully infringe or contributorily infringe or induce others to infringe the '643 and/or '880 patents, making this an exceptional case and justifying the assessment of increased damages pursuant to 35 U.S.C. §284 and the award of attorneys' fees pursuant to 35 U.S.C. §285.

#### **COUNT THREE: FEDERAL TRADEMARK DILUTION**

- 44. Paragraphs 1 through 43 are repeated and realleged as if fully set forth herein.
- 45. KCI's V.A.C. and Vacuum Assisted Closure trademarks are famous marks within the meaning of 15 U.S.C. § 1125(c)(1).
- 46. Defendants' use of V.A.C. and/or Vacuum Assisted Closure and confusingly similar designations is likely to dilute the distinctive quality of KCI's trademarks.
- 47. The actions of Defendants constitute trademark dilution in violation of federal Lanham Act, 15 U.S.C. § 1125(c).
  - 48. Said trademark dilution is irreparably injuring the goodwill of KCI.
- 49. Defendants' dilution of KCI's V.A.C. and/or Vacuum Assisted Closure trademarks has been willful with intent to trade on KCI's reputation or to cause dilution of KCI's trademarks.

- 50. Pursuant to 15 U.S.C. §§ 1125(c)(2) and 1117(a), KCI is entitled to damages for Defendants' trademark dilution, an accounting for profits made by Defendants on sales of the Versatile 1 System, and recovery of KCI's costs of this action.
- 51. The acts of Defendants make this an exceptional case entitling Plaintiffs to recover their reasonable attorneys' fees pursuant to 15 U.S.C. §§ 1125(c)(2) and 1117(a).
- 52. Defendants' dilution of KCI's trademarks has irreparably injured KCI's goodwill and diluted its share of the negative pressure wound therapy market, and unless enjoined by this Court, will continue to do so.
- 53. Pursuant to 15 U.S.C. § 1125(c)(1), Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing dilution of the V.A.C. and/or Vacuum Assisted Closure trademarks.

## COUNT FOUR: VIOLATION OF TEXAS ANTI-DILUTION STATUTE

- 54. Paragraphs 1 through 53 are repeated and realleged as if fully set forth herein.
- 55. KCI's V.A.C. and Vacuum Assisted Closure trademarks are famous marks within the meaning of 15 U.S.C. § 1125(c)(1).
- 56. Defendants' use of V.A.C. and/or Vacuum Assisted Closure, and confusingly similar designations, has diluted the distinctive quality of KCI's V.A.C. and/or Vacuum Assisted Closure trademarks and has injured KCI's business reputation.
- 57. Defendants' use of V.A.C. and/or Vacuum Assisted Closure and confusingly similar designations is likely to dilute the distinctive quality of KCI's trademarks.
- 58. The actions of Defendants constitute trademark dilution in violation of Texas Business and Commerce Code § 16.29.
  - 59. Said trademark dilution is irreparably injuring the goodwill of KCI.

- 60. Defendants' dilution of KCI's V.A.C. and/or Vacuum Assisted Closure trademarks has been willful with intent to trade on KCI's reputation or to cause dilution of KCI's trademarks.
- 61. Defendants' dilution of KCI's trademarks has irreparably injured KCI's goodwill and diluted its share of the negative pressure wound therapy market, and unless enjoined by this Court, will continue to do so.
- 62. Pursuant to Texas Business and Commerce Code § 16.29, Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing dilution of the V.A.C. and/or Vacuum Assisted Closure trademarks and from injuring KCI's business reputation.

#### **COUNT FIVE: FEDERAL FALSE ADVERTISING**

- 63. Paragraphs 1 through 62 are repeated and realleged as if fully set forth herein.
- 64. The Defendants' public statements and false representations, including but not limited to numerous emails, letters, banners and other communications characterizing negative pressure wound therapy systems, like the V.A.C. System, as being no different that the general purpose suction pumps such as BlueSky's Versatile 1 System constitute false statements.
  - 65. Said representations, whether express or implied, are false.
- 66. Said representations, whether express or implied, have a tendency to deceive health care providers, group purchasing organizations, the United States government and others (collectively herein, "Health Care Providers").
- 67. Said false or deceptive representations are material to the purchasing and/or reimbursement practices of Health Care Providers in that the representations are causing Health Care Providers to purchase the Versatile 1 System.

- 68. Said false or deceptive representations are injuring the goodwill of KCI and its high quality V.A.C. System because they are causing Health Care Providers to believe that the Versatile 1 System is an effective alternative to the V.A.C. System, when in fact it is not.
- 69. The actions of Defendants constitute false or misleading representations of fact in commercial advertising or promotion concerning the nature, characteristics, or qualities of the Versatile 1 System in violation of federal Lanham Act, 15 U.S.C. § 1125(a)(1)(B).
- 70. Pursuant to 15 U.S.C. § 1117(a), Plaintiffs are entitled to damages for Defendants' false advertisements and an accounting of profits made by Defendants on the sale of the Versatile 1 System, and recovery of Plaintiffs' costs of this action.
- 71. Defendants' false advertisement of the Versatile 1 System have been made willfully and wantonly for the purpose of deceiving Health Care Providers, the United States government and others, inducing them to utilize the Versatile 1 System in the mistaken belief that it is identical or equivalent to the V.A.C. System, and injuring the goodwill of KCI.
- 72. The acts of Defendants make this an exceptional case entitling Plaintiffs to recover their attorneys' fees pursuant to 15 U.S.C. § 1117(a).
- 73. Defendants' false advertisements are irreparably injuring Plaintiffs' goodwill and eroding Plaintiffs' share of the negative pressure wound therapy market, and unless enjoined by this Court, will continue to do so.
- 74. Pursuant to 15 U.S.C. § 1116(a), Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing false advertisements.

#### **COUNT SIX: FEDERAL UNFAIR COMPETITION**

75. Paragraphs 1 through 74 are repeated and realleged as if fully set forth herein.

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- 76. The actions of Defendants constitute unfair competition with KCI in violation of federal Lanham Act, 15 U.S.C. § 1125(a).
- 77. Pursuant to 15 U.S.C. § 1117(a), KCI is entitled to damages for Defendants' unfair competition, an accounting of profits made by Defendants on sales of the Versatile 1 System, and recovery of KCI's costs of this action.
- 78. Defendants' false or misleading representations and descriptions and other acts complained of herein, are likely to cause confusion, or association of Defendants with KCI, or as to the origin, sponsorship, or approval of Defendants' goods, services, or commercial activities.
- 79. Defendants' false or misleading representations and descriptions and other acts complained of herein, misrepresent the nature, characteristics, qualities, or origin of Defendants' goods, services, or commercial activities.
- 80. Defendants' unfair competition with KCI has been willful and wanton for the purpose of deceiving others and injuring the goodwill of KCI.
- 81. Defendants' acts of unfair competition make this an exceptional case entitling Plaintiffs to recover their reasonable attorneys' fees pursuant to 15 U.S.C. § 1117(a).
- 82. Defendants' acts of unfair competition are irreparably injuring KCI's goodwill and eroding KCI's share of the negative pressure wound therapy market, and unless enjoined by this Court, will continue to do so.
- 83. Pursuant to 15 U.S.C. § 1116(a), KCI is entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing acts of unfair competition.

#### COUNT SEVEN: FEDERAL TRADEMARK INFRINGEMENT

- 84. Paragraphs 1 through 83 are repeated and realleged as if fully set forth herein.
- 85. KCI's V.A.C. and Vacuum Assisted Closure trademarks are distinctive of KCI's patented V.A.C. System, and indicate to hospitals, group purchasing organizations and the United States government that every system used for negative pressure wound therapy comes from a single source, KCI.
- 86. KCI's distinctive V.A.C. and Vacuum Assisted Closure trademarks symbolize the goodwill of KCI, which is the result of its significant promotion and distribution of the high quality V.A.C. System.
- 87. Defendants' use in commerce of the V.A.C. and Vacuum Assisted Closure trademarks and the phrase "Vacuum Assisted Wound Therapy" or other confusingly similar designations is likely to cause confusion, or to cause mistake, or to deceive as to the origin of the Versatile 1 System. Such use is likely to cause Health Care Providers to believe that the Versatile 1 System and the V.A.C. System come from the same source, or that KCI or Defendants sponsor or approve the pump of the other, or that KCI and Defendants are somehow affiliated, connected or associated with one another when in fact they are not.
- 88. Defendants' use in commerce of the V.A.C. and/or Vacuum Assisted Closure trademarks, and/or confusingly similar designations, in connection with the Versatile 1 System is injuring the goodwill of KCI and its high quality V.A.C. System.
- 89. The actions of Defendants constitute trademark infringement in violation of the federal Lanham Act, 15 U.S.C. § 1117(a)(1)(A).

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- 90. Pursuant to 15 U.S.C. § 1117(a), KCI is entitled to damages for Defendants' trademark infringement, an accounting of profits made by Defendants on sales of the Versatile 1 System, and recovery of KCI's costs of this action.
- 91. Defendants have willfully and wantonly infringed on KCI's V.A.C. and/or Vacuum Assisted Closure trademarks, and their actions have been calculated to confuse, mislead or deceive Health Care Providers, and to injure the goodwill of KCI.
- 92. The acts of Defendants make this an exceptional case, entitling Plaintiffs to recover their reasonable attorneys' fees pursuant to 15 U.S.C. § 1117(a).
- 93. Defendants' infringement of KCI's trademarks is irreparably injuring KCI's goodwill and eroding KCI's share of the negative pressure wound therapy market, and unless enjoined by this Court, will continue to do so.
- 94. Pursuant to 15 U.S.C. § 1116(a), KCI is entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing trademark infringement.

#### **COUNT EIGHT: COMMON LAW TRADEMARK INFRINGEMENT**

- 95. Paragraphs 1 through 94 are repeated and realleged as if fully set forth herein.
- 96. Defendants' acts constitute trademark infringement under the applicable common law.
- 97. Defendants' acts of trademark infringement entitle KCI to recover damages and costs of this action, together with an accounting of profits made by Defendants on sales of the Versatile 1 System.
- 98. The acts of Defendants have been malicious and calculated to injure KCI. The willful, wanton and malicious nature of Defendants' conduct entitles Plaintiffs to an award of their reasonable attorneys' fees and punitive damages against Defendants.

- 99. Defendants' infringement of KCI's trademarks is irreparably injuring KCI's goodwill and eroding KCI's share of the negative pressure wound therapy market, and unless enjoined by this Court, will continue to do so.
- 100. Under the applicable common law, KCI is entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing trademark infringement.

## COUNT NINE: COMMON LAW NEGLIGENT INTERFERENCE WITH PROSPECTIVE ECONOMIC RELATIONS

- 101. Paragraphs 1 through 100 are repeated and realleged as if fully set forth herein.
- 102. An economic relationship exists between Plaintiff KCI and third parties; specifically between KCI and Health Care Providers. Furthermore, economic relationships exist between KCI and the United States government by virtue of KCI's status as a participating Medicare distributor.
- 103. There is a significant probability of future economic benefit to Plaintiff KCI by virtue of these relationships.
- 104. Defendants at all relevant times knew or should have known of these economic relationships as exhibited by their objectively false statements to the United States government, Health Care Providers, the public, and other third parties.
- 105. Defendants' negligent and wrongful acts were designed to induce breach or disruption of these contractual relationships. Moreover, Defendants' acts were compelled by an improper motive. Therefore, Defendants' conduct falls outside the realm of legitimate business transactions.
- 106. Moreover, actual disruptions of these economic relationships have occurred as a result of Defendants' negligent, unlawful and wrongful acts.

107. Plaintiff KCI has suffered economic harm proximately caused by the acts of Defendants because they are causing Health Care Providers to believe that the Versatile 1 System is an effective alternative to the V.A.C. System.

## COUNT TEN: COMMON LAW TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC RELATIONS

- 108. Paragraphs 1 through 107 are repeated and realleged as if fully set forth herein.
- between KCI and Health Care Providers. Furthermore, economic relationships exist between KCI and the United States government by virtue of KCI's status as a participating Medicare provider. In addition, economic relationships exist between KCI and the United States government by virtue of the fact that KCI is a third party beneficiary of economic relationships between the government and the users of negative pressure wound therapy equipment.
- 110. There is a significant probability of future economic benefit to Plaintiff KCI by virtue of these relationships.
- 111. Defendants at all relevant times knew or should have known of these economic relationships as exhibited by their objectively false statements to the United States government, Health Care Providers, the public, and other third parties.
- 112. Defendants' intentional, malicious and wrongful acts were designed to induce breach or disruption of these economic relationships. Moreover, Defendants' acts were compelled by an improper motive. Therefore, Defendants' conduct falls outside the realm of legitimate business transactions.
- 113. Moreover, actual disruptions of these economic relationships have occurred as a result of Defendants' unlawful and wrongful acts.

114. Plaintiff KCI has suffered economic harm proximately caused by the acts of Defendants because they are causing Health Care Providers to believe that the Versatile 1 System is an effective alternative to The V.A.C. System.

## COUNT ELEVEN: COMMON LAW TORTIOUS INTERFERENCE WITH CONTRACTUAL RELATIONS

- 115. Paragraphs 1 through 114 are repeated and realleged as if fully set forth herein.
- KCI and Health Care Providers. Furthermore, valid contract and relationships exist between KCI and the United States government by virtue of KCI's status as a participating Medicare provider. In the alternative, KCI is a third party beneficiary of contracts between the United States government and purchasers and users of negative pressure wound therapy equipment.
- 117. Defendants have and at all relevant times had knowledge of these contracts as exhibited by their statements to the United States government, Health Care Providers, the public, and other third parties.
- 118. Defendants' intentional and malicious acts were designed to induce breach or disruption of these contractual relationships.
- 119. Moreover, actual breaches and/or disruptions of these contractual relationships have occurred as a result of Defendants' unlawful acts.
- 120. Defendants' intentional and malicious acts are resulting in pecuniary loss to KCI and injuring the goodwill of KCI and its high quality V.A.C. System because they are causing Health Care Providers to believe that the Versatile 1 System is an effective alternative to the V.A.C. System.

#### COUNT TWELVE: COMMON LAW PRODUCT DISPARAGEMENT

121. Paragraphs 1 through 120 are repeated and realleged as if fully set forth herein.

- 122. Defendants' false statements and publications, including on the BlueSky website, and in numerous emails, letters, banners and other communications, constitute false statements that characterize negative pressure wound therapy systems, like the V.A.C. System, as being no different that the general purpose suction pumps, such as BlueSky's Versatile 1 System.
- 123. BlueSky's statements infer that the quality of the V.A.C. System is not worthy of reimbursement or federal trademark and/or patent protection or that the V.A.C. System does not have effective patent protection.
- 124. These statements when viewed in their broad context, which includes the general tenor of the work, the subject of the statements, the setting, and the format of the work are misleading and objectively factual.
- 125. The specific context and content of the statements, analyzing the extent of figurative or hyperbolic language used and the reasonable expectations of the audience in that particular situation, is deceptive and misleading.
- 126. The statements are sufficiently factual to be susceptible to being proven true or false. BlueSky's statements are clearly factual and, as such, are easily disproved.
  - 127. Said representations, whether express or implied, are false.
- 128. Said representations, whether express or implied, have a tendency to deceive doctors, group purchasing organizations, hospitals and others.
- 129. Said false or deceptive representations are material to the purchasing practices and/or reimbursement practices of hospitals and group purchasing organizations in that the representations are causing Health Care Providers, to purchase the Versatile 1 System in place of the V.A.C. System.

- 130. Said false or deceptive representations are injuring the goodwill of KCI and its high quality V.A.C. System because they are causing Health Care Providers, to believe that the Versatile 1 System is an effective alternative to the V.A.C. System.
- 131. Said false or deceptive representations have caused KCI to suffer pecuniary loss because they are causing Health Care Providers, to purchase the Versatile 1 System for use in negative pressure wound therapy.
- 132. Since BlueSky's actions are likely to deceive the reasonable wound therapy consumer and KCI has suffered and continues to suffer pecuniary loss, and as such BlueSky's conduct constitutes product disparagement under the applicable common law.

#### COUNT THIRTEEN: COMMON LAW TRADE LIBEL

- 133. Paragraphs 1 through 132 are repeated and realleged as if fully set forth herein.
- 134. The posting of press releases on the BlueSky website and the numerous emails, letters, banners and other communications, characterizing negative pressure wound therapy systems, like the V.A.C. System, as being no different that the general purpose suction pumps such as BlueSky's Versatile 1 System constitute false statements.
- 135. BlueSky's statements infer that the quality of the V.A.C. System is not worthy of reimbursement levels or the price charged by KCI, or worthy of federal trademark and/or patent protection and that the V.A.C. System does not have effective patent protection.
- 136. These statements when viewed in their broad context, which includes the general tenor of the work, the subject of the statements, the setting and the format of the work, are misleading and objectively factual.

- 137. The specific context and content of the statements, analyzing the extent of figurative or hyperbolic language used and the reasonable expectations of the audience in that particular situation, is deceptive and misleading.
- 138. The statements are sufficiently factual to be susceptible to being proved true or false. The V.A.C. System is the only system currently cleared by the Center for Medicare and Medicaid Services ("CMS") for use in negative pressure wound therapy in home health care, and is patented and clearly different than the Versatile 1 System. BlueSky's statements to the contrary are clearly factual and as such, are easily disproved.
  - 139. Said representations, whether express or implied, are false.
- 140. Said representations, whether express or implied, have a tendency to deceive doctors, group purchasing organizations, hospitals and others.
- 141. Said false or deceptive representations are material to the purchasing practices and/or reimbursement practices of Health Care Providers in that the representations are causing Health Care Providers to purchase the Versatile 1 System for use in negative pressure wound therapy.
- 142. Said false or deceptive representations are injuring the goodwill of KCI and its high quality V.A.C. System because they are causing Health Care Providers to believe that the Versatile 1 System is an effective and approved alternative to The V.A.C. System.
- 143. Said false or deceptive representations have caused KCI to suffer pecuniary loss because they are causing Health Care Providers to purchase the Versatile 1 System for use in negative pressure wound therapy.

144. Because BlueSky's actions are likely to deceive the reasonable wound therapy consumer and KCI has suffered and continues to suffer pecuniary loss, BlueSky's conduct constitutes trade libel under applicable common law.

#### **COUNT FOURTEEN: COMMON LAW UNFAIR COMPETITION**

- 145. Paragraphs 1 through 144 are repeated and realleged as if fully set forth herein.
- 146. Defendants' illegal acts constitute unfair competition under the common law of the State of Texas.
- 147. As set forth elsewhere in this complaint, Defendants' acts interfered with Plaintiffs' ability to conduct its business.
- 148. Furthermore, through its acts, Defendants have appropriated and used, in competition with the Plaintiffs, several unique pecuniary interests created by the Plaintiffs through the expenditure of Plaintiffs' labor, skill and money.
- 149. Plaintiffs' pecuniary interests, which Defendants have appropriated and used, include, but are not limited to, Plaintiffs' patents and trademarks, the goodwill Plaintiffs have developed for themselves and for their products, and the health care market's appreciation of the value and therapeutic benefit of Plaintiffs' V.A.C. System.
- 150. Defendants' misappropriation has been without Plaintiffs' permission or authority and in competition with Plaintiffs' own licensing programs.
- 151. Defendants' acts of unfair competition entitle Plaintiffs to recover its damages and costs of this action, together with an accounting of profits made by Defendants on sales of their pumps, dressings, and other accessories.
- 152. Defendants' acts of unfair competition have been malicious and calculated to injure Plaintiffs.

- 153. The willful, wanton and malicious nature of Defendants' conduct entitles Plaintiffs to an award of their reasonable attorney's fees and punitive damages against Defendants.
- 154. Defendants' acts of unfair competition are irreparably injuring Plaintiffs' goodwill and eroding Plaintiffs' share of the wound healing market, and unless enjoined by this Court, will continue to do so and cause damage to Plaintiffs.
- 155. Under the common law of the State of Texas, Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing acts of unfair competition.

#### V. JURY DEMAND

Plaintiffs hereby request a trial by jury.

#### VI. PRAYER

For these reasons, Plaintiffs ask for judgment against Defendants for the following:

- A. Defendants, their officers, agents, servants, employees, successors, assigns and attorneys, and all persons in active concert or participation with any of them, be preliminarily and permanently enjoined from the following:
  - 1. Any further acts of infringement or contributory infringement or inducing others to infringe U.S. Patent Nos. 5,636,643 and 4,969,880;
  - 2. Any further acts of infringement or contributory infringement or inducing others to infringe on KCI's V.A.C. and Vacuum Assisted Closure trademarks;
  - 3. Imitating, copying or making unauthorized use of KCI's V.A.C. and Vacuum Assisted Closure trademarks;
  - 4. Manufacturing, producing, distributing, circulating, selling, offering for sale, advertising, promoting or displaying any product bearing any simulation, reproduction, counterfeit, copy or colorable imitation of KCI's V.A.C. or Vacuum Assisted Closure trademarks, including but not limited to the Versatile 1 System;

- 5. Using any simulation, reproduction, counterfeit, copy or colorable imitation of KCI's V.A.C. or Vacuum Assisted Closure trademarks in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation or distribution of any product in such a fashion as to relate or connect, or tend to relate or connect, such product in any way to KCI, or to the goods, including the V.A.C. System, sold or manufactured or sponsored by, or connected with, KCI;
- 6. Making any statement or representation whatsoever, or using any false designation of origin or false description (including without limitation, any letters or symbols), or performing any act in commerce, which can be or is likely to lead to the trade or public or individual members thereof to believe that any products manufactured, distributed or sold by Defendants are in any manner associated or connected with KCI or the V.A.C. System, or are sold, manufactured, licensed, sponsored, approved or authorized by KCI;
- 7. Directly or indirectly falsely advertising or promoting or selling the Versatile 1 System;
- 8. Making or inducing others to make any false, misleading or deceptive statement of fact, or representation of fact in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation or distribution of the Versatile 1 System or of any product in such a fashion as to suggest that such product is equivalent to or a substitute for, or has the same qualities or characteristics as, Plaintiffs' V.A.C. System;
- 9. Diluting the distinctive quality of KCI's V.A.C. and/or Vacuum Assisted Closure trademarks; and
- 10. Unfairly competing with KCI.
- B. Defendants, their officers, agents, servants, employees, successors, assigns and attorneys, and all persons in active concert or participation with any of them, be ordered to deliver up for destruction, and recall from their suppliers and distributors for like delivery and destruction, all products, labels, signs, plates, packages, dies, wrappers, receptacles and advertisements in their possession or under their control bearing the following:
  - 1. any words, terms, names, symbols, devices, or any combination thereof, which misrepresent the nature, characteristics or qualities of the Versatile 1 System, and all plates, molds, matrices and other means of making the same;

- 2. any markings similar to KCI's V.A.C. or Vacuum Assisted Closure trademarks or any simulation, reproduction, counterfeit, copy or colorable imitation thereof, and all plates, molds, matrices and other means of making the same; and/or
- 3. any words, terms, names, symbols, devices, or any combination thereof, which are similar to, or dilute the distinctive quality of, KCI's V.A.C. and/or Vacuum Assisted Closure trademarks and all plates, molds, matrices and other means of making the same.
- C. Plaintiffs be granted such other relief as the court may deem appropriate to correct and to prevent the trade and public from deriving any erroneous impression (i) concerning the nature, characteristics or qualities of Defendants' Versatile 1 System; and (ii) that any product manufactured, sold or otherwise circulated or promoted by Defendants are approved for negative pressure wound therapy, or in any way related to KCI, or the V.A.C. System.
- D. Defendants be ordered to take corrective action to correct any erroneous impression the public may have derived concerning the nature, characteristics or qualities of Defendants' Versatile 1 System, including without limitation the placement of corrective advertising.
- E. Plaintiffs recover all damages they have sustained as a result of Defendants' infringement, unfair competition and other illegal acts.
- F. Plaintiffs be awarded increased damages under 15 U.S.C. § 1117(a), 15 U.S.C. §§ 1125(c)(2) and 35 U.S.C. §284.
- G. Plaintiffs be awarded punitive damages for Defendants' willful and malicious infringement, unfair competition and other illegal acts.
- H. The court declare that this is an exceptional case pursuant to 35 U.S.C. §285 and 15 U.S.C. §§ 1125(c)(2) and 1117(a) and award Plaintiffs their reasonable attorney fees, costs, and increased damages.

- I. Plaintiffs recover their costs and expenses for prosecuting this action and prejudgment and postjudgment interest.
- J. Plaintiffs recover all other relief the court deems appropriate.

Respectfully submitted,

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KINETIC CONCEPTS, INC. and
KCI LICENSING, INC. and
KCI USA, INC. and
WAKE FOREST UNIVERSITY HEALTH
SCIENCES

# UNITED STATES DISTRICT COURT WESTERN DISTRICT OF TEXAS SAN ANTONIO DIVISION

## NOTICE OF DOCUMENT(S) NOT IMAGED AND CONTAINED IN CASE FILE

Civil Case No.

SA-03-CA-832-RF

Kinetic Concepts, Inc. et al

VS.

Bluesky Medical Corp. et al.

Attachments to Document No.2

Document Description:

Plaintiffs' First Amended

Complaint

Filed By:

**Plaintiffs** 

File Date:

September 8, 2003

Ruth R. Guerrero DEPUTY CLERK